Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-7800.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
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Preface

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CDRH

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Additional copies of this guidance are also available from the Center for Biologics Evaluation and Research (CBER), by written request, Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Avenue, Rm. 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-7800, by email, ocod@fda.hhs.gov, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff or Office responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

This draft guidance provides information on how to notify FDA of the transfer of a 510(k) clearance from one person to another, and the procedures FDA and industry should use to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up-to-date.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Each person who is required to register must obtain FDA clearance of a premarket notification (510(k)) prior to introducing or delivering for introduction into interstate commerce for commercial distribution a device intended for human use that is not 510(k)-exempt.[1] However, when a 510(k) clearance for a specific device is sold or transferred from

[1] See Federal Food, Drug, and Cosmetic Act (FD&C Act) sections 510(k), 513(i), and 515 (21 U.S.C. §§ 360(k), 360c(i), and 360e) and 21 CFR 807.81(a), 807.100(a).

one person to another and the device is not significantly changed or modified, FDA does not expect the submission of a new 510(k).[2] FDA commonly receives notifications from individuals claiming that a 510(k)-clearance has been transferred to them from a previous 510(k) holder. Tracking such transfers, however, has been challenging because FDA has been unable to identify and contact all previous 510(k) holders to establish a sequence of historical transfers of a particular 510(k). Until recently, FDA's databases did not reflect changes in the 510(k) holder that occurred after FDA's clearance of the 510(k). This was in part because 510(k) holders were not required to list their devices by *510(k) number*, which made it difficult for FDA to tie a particular 510(k) to its current holder. Lack of updated, accurate 510(k) holder information created a number of challenges for FDA, for current 510(k) holders, future 510(k) submitters, and other stakeholders.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-85) amended section 510 of the FD&C Act by requiring domestic and foreign device establishments to begin submitting their registration and device listing information to FDA by electronic means rather than on paper forms,[3] and also specified the timeframes within which establishments are required to submit such information.[4] In accordance with FDAAA, the agency launched FDA's Unified Registration and Listing System (FURLS), an Internet-based registration and listing system.[5]

On August 2, 2012, FDA modified the regulations in 21 CFR part 807 to reflect statutory amendments to the device registration and listing provisions of the FD&C Act.[6] FDA also added a requirement that the FDA-assigned premarket submission number of cleared 510(k) devices be included with device listing information.[7] When an owner or operator creates a listing for a 510(k) device as a manufacturer, specification developer, repacker/relabeler, single-use device reprocessor, or remanufacturer, this signals to FDA that they are the current 510(k) holder for that device, because these entities are responsible for the commercial distribution of the device. Listing information is required to be updated at least annually[8] and there may only be one 510(k) holder for a device at a time;[9] therefore, this provides FDA with current 510(k) holder information by 510(k) number.

III. Definitions

For purposes of this guidance, we will use the following definitions:

[2] See 21 CFR 807.81(a) and 42 FR 42523 (August 23, 1977).
[3] See FD&C Act section 510(p) (21 U.S.C. § 360(p)).
[4] See FD&C Act sections 510(b)(2), (i), and (j) (21 U.S.C. §§ 360(b)(2), (i), and (j)).
[5] See 77 FR 45927 (August 2, 2012).
[6] See id.
[7] See 21 CFR 807.25(g)(4).
[8] See FD&C Act section 510(j) (21 U.S.C. § 360(j)) and 21 CFR 807.22.
[9] See FD&C Act section 510(k) (21 U.S.C. § 360(k)) and 21 CFR 807.81(a).

1. **"510(k) device"**

   - a device which was found to be substantially equivalent to another device under sections 513(f)(1) and 513(i) of the FD&C Act (21 U.S.C. §§ 360c(f)(1) and (i))

2. **"Person"**

   - includes individuals, partnerships, corporations, and associations as defined under section 201(e) of the FD&C Act (21 U.S.C. § 321(e))

3. **"510(k) holder"**

   - the person who possesses the 510(k) clearance for a device (an FDA determination that a particular device has been found to be substantially equivalent to another device under sections 513(f)(1) and 513(i) of the FD&C Act) (21 U.S.C. §§ 360c(f)(1) and (i))

IV. Access to Current 510(k) Holder Information

1. How can I obtain information on the current holder of a 510(k) that is under the purview of CDRH if I know the 510(k) number?

To find information about the current holder of a CDRH 510(k):

- Locate the CDRH 510(k) database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm)
- Type the 510(k) number in the "510K Number" field[10]
- Click on the "Search" button
- FDA plans to link the 510(k) database to FURLS, which will provide the most up to date information available on the current holder of a 510(k).

The CDRH 510(k) database is publicly available. By linking the CDRH 510(k) database to FURLS, FDA is using information from the FURLS database to provide the most up-to-date information available on the current holder of a 510(k).

2. How can I obtain information on the current holder of a 510(k) that is under the purview of CBER if I know the 510(k) number?

Information about the current holder of a CBER 510(k) should also be available in the CDRH 510(k) database as described above for CDRH 510(k)s. If you cannot locate the 510(k) in the

[10] Other terms entered into this search function may also locate the 510(k) and the current holder of the 510(k), but using the 510(k) number when available is recommended as the most efficient way to obtain this information.

CDRH 510(k) database, information is also available on CBER's website. (http://www.fda.gov/BiologicsBloodVaccines/ucm121134.htm)

V. Questions and Answers on Notifying FDA of a Transfer of a 510(k) Clearance

1. When should I report that I have bought, sold, or otherwise transferred a 510(k) clearance?

Notification of FDA of a sale or other transfer of a 510(k) clearance, whether or not the device is already on the market, is accomplished via compliance with listing requirements. As discussed above, as a result of the launch of the FURLS Device Registration and Listing Module (DRLM) and the changes to the registration and listing regulations that became effective on October 1, 2012,[11] the medical device listing information provided to FDA has changed. Owners and operators of medical device establishments that market 510(k)-cleared devices must now supply the FDA-assigned premarket submission number of the cleared 510(k) when they list their devices in FURLS.[12] This allows FDA to easily identify the holder of each 510(k) based on the records created by manufacturers, specification developers, repackers/relabelers, single-use device reprocessors, or remanufacturers in FURLS DRLM. Because contract manufacturers and sterilizers, foreign exporters, and foreign private label distributors are not responsible for the commercial distribution of devices, they would not be 510(k) holders, and should list the product under their customer's 510(k) number once it has been listed by the 510(k) holder. Any entity that fails to list as required renders the device misbranded.[13]

New establishments are required to register and list within 30 days of entering into an operation described in 21 CFR 807.20(a).[14] In addition, 510(k) holders are required to review and update their Registration[15] and Listing[16] information at least annually. Persons may also update their Registration and Listing information at other times, for example subsequent to a sale or purchase of a 510(k), instead of waiting for the requisite annual update.[17] There is no fee additional to the annual registration fee for such updates.

2. What happens if more than one person claims to be the 510(k) holder for a particular device at the same time?

If two persons claim to be the 510(k) holder for a particular device, for example by registering and listing the same 510(k) number during the same annual registration and listing

[11] See 77 FR 45927 (August 2, 2012).
[12] See 21 CFR 807.25(g)(4).
[13] See FD&C Act sections 502(o) and 510(j) (21 U.S.C. §§ 352(o) and 360(j)).
[14] See 21 CFR 807.22(a).
[15] See FD&C Act section 510(b)(2) (21 U.S.C. § 360(b)(2)) (Domestic) and 21 CFR 807.22(b)(1); FD&C Act section 510(i) (21 U.S.C. § 360(i)) (Foreign).
[16] See FD&C Act section 510(j)(2) (21 U.S.C. § 360(j)(2)) and 21 CFR 807.22(b)(3).
[17] See 21 CFR 807.22(b)(4).

period, the database will show the person who listed their device most recently until the issue is resolved. FDA will contact both persons claiming to be the 510(k) holder and attempt to determine the rightful 510(k) holder. In the event of a dispute, a court order, attestation from a previous, uncontested 510(k) holder, legal instrument such as a contract or will, and/or other documentation of the sequence of historical transfers of the 510(k) clearance, up to and including the current holder, may be submitted as evidence to establish the current 510(k) holder and support updating the information in the FURLS database. The person determined not to be the 510(k) holder would be in violation of the FD&C Act if they were marketing a device without required 510(k) clearance.

3. Who should maintain information documenting the transfer of a 510(k) clearance?

We recommend that the current 510(k) holder maintain information documenting the transfer of a 510(k) clearance in its 510(k) files.

VI. Question and Answer about CLIA Categorizations

1. What should I submit upon transfer of a 510(k) clearance to ensure the CLIA categorization of my device is accurate?

FDA is responsible for the categorization of commercially marketed in vitro diagnostic tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[18] FDA recommends that where the name of a cleared device changes, or the name of the manufacturer or distributor changes, the manufacturer should submit the updated label to FDA so FDA can ensure that the CLIA categorization of the device is accurate and update its record of the categorized test with the appropriate 510(k) holder and device information. See "Guidance for Industry and FDA Staff: Administrative Procedures for CLIA Categorization," available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070762.htm. The new 510(k) holder should submit a letter to the Agency (at U.S. Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center – WO66-G609, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002) citing the 510(k) number, and identifying the submission as a CLIA Categorization Update. The new 510(k) holder should include a copy of the package insert that will be distributed with the device.

[18] See 64 FR 73561(December 30, 1999).